**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
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May 26, 2015

Applied Medical Technology, Inc.
Joshua D. Meinke
QA/Regulatory Supervisor
8006 Katherine Blvd.
Brecksville, OH 44141

Re: K142971
Trade/Device Name: AMT Bridle - Nasal Tube Retention System
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: April 23, 2015
Received: April 24, 2015

Dear Joshua D. Meinke,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K142971

Device Name
AMT Bridle - Nasal Tube Retention System

Indications for Use *(Describe)*
The AMT Bridle - Nasal Tube Retention System is indicated to prevent inadvertent displacement or removal of Nasogastric/Nasointestinal (NG/NI) tubes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# SECTION – 5

## 510(K) Summary

AMT Bridle™ – Nasal Tube Retention System

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| **Date Prepared:** | May 26, 2015 |
| **Submitter:** | Joshua D. Meinke<br>QA/Regulatory Supervisor<br>Applied Medical Technology, Inc.<br>8006 Katherine Boulevard<br>Brecksville, OH 44141<br>Phone: 440-717-4252<br>Fax: 440-717-4200<br>Email: Joshua.Meinke@appliedmedical.net<br><br>Contact Person: Joshua Meinke |
| **Device Information:** | Trade Name: AMT Bridle™ - Nasal Tube Retention System<br>Common Name: Nasal Tube Fixation Device<br>Classification Name: Gastroenterology and Urology (21 CFR 876.5980)<br>Regulatory Class: II<br>Product Code: KNT |
| **Predicate Device:** | AMT Nasogastric Bridle™ System with Magnet Retrieval<br>(cleared under K030784) |
| **Intended Use:** | The AMT Bridle™ – Nasal Tube Retention System is a device placed around the vomer bone of the nasal septum and attached to a Nasogastric/Nasointestinal (NG/NI) tube to prevent inadvertent displacement or removal of the nasal tube. |
| **Device Description:** | The AMT Bridle™ – Nasal Tube Retention System is placed around the vomer bone of the nasal septum and attached to a nasogastric/nasointestinal (NG/NI) tube to prevent inadvertent displacement or removal of the tube. The AMT Bridle™ – Nasal Tube Retention System consists of a retrieval probe, catheter with stylet guide, a nasal tube clip, and removal pick. The AMT Bridle™ retrieval probe and catheter are the device components inserted through the patient's nares with the probe magnetically retrieving the catheter and creating a loop around the vomer bone. The nasal tube clip is the component directly attached to both the nasal tube and bridle catheter loop to hold the tube in place. |

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| **Technological Characteristics:** | The AMT Bridle™ – Nasal Tube Retention System is provided non-sterile for single use only in a healthcare facility or unit. The AMT Bridle™ is provided in two different configurations, a standard size and a smaller Micro sized design. Description of each device type is described below:<br><br>AMT Bridle™:<br>Probe size: Larger diameter and longer length compared to AMT Micro Bridle™<br>Catheter Size: Same diameter as AMT Micro Bridle™, longer length<br>Clip Sizes(FR): 08 - 18 FR<br>Clip Thickness: Double thickness of AMT Micro Bridle™<br>Part Number Scheme: 4-41XX (where XX = French size of clip)<br><br>AMT Micro Bridle™:<br>Probe size: Smaller diameter and shorter length compared to AMT Bridle™<br>Catheter Size: Same diameter as AMT Bridle™, shorter length<br>Clip Sizes: 05 - 08 FR<br>Clip Thickness: Half thickness of AMT Bridle™<br>Part Number Scheme: 4-41XXM (where XX = French size of clip)<br><br>The standard and Micro designs maintain the same materials, manufacturing methods, and instructions for use. Both devices are made from DEHP and Latex free materials. Both designs incorporate the same components inside of a kit, including the retrieval probe, catheter with stylet guide, nasal tube clip, and removal pick. Placement of both devices is identical with the nasal clip attaching the Bridle loop to the Nasal tube, securing the tube in place by connection to the vomer bone. |
| **Biocompatibility Testing:** | The AMT Bridle – Nasal Tube Retention System has been tested for prolonged contact (less than or equal to 30 days) to the applicable sections of the following standards:<br>• ISO 10993-1: 2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process<br>• ISO 10993-5: 2009 Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity<br>• ISO 10993-6: 2007 Biological Evaluation of Medical Devices – Part 6: Tests for local effects after implantation<br>• ISO 10993-10: 2010 Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization<br>• ISO 10993-11:2006 Biological Evaluation of Medical Devices – Part 11: Tests for systemic toxicity<br>• ISO 10993-12:2007 Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials<br><br>An independent risk assessment was completed for the above biocompatibility testing and it was determined that the biocompatibility results for the AMT Bridle – Nasal Tube Retention System met the acceptance criteria for prolonged contact (less than or equal to 30 days). |

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| **Performance Testing:** | AMT conducted various performance tests on all components contained within the AMT Bridle® - Nasal Tube Retention System. Testing found that all components and materials met or exceeded design specifications established and cleared under K030784. The following tests were used to show substantial equivalence:<br><br>• Clip hinge and teeth integrity<br>• Retention force<br>• Bond strength of material joints<br>• Tape pullout force<br>• Usability testing<br>• Shelf life testing<br><br>Bridle catheter, stylet guide, and probe designs remain very similar or the same as the predicate device cleared under K030784, so performance testing remains ultimately unchanged. Several performance tests were conducted for the new clip sizes to ensure that molded parts maintained the required performance specifications. Bridle clips passed all performance testing for hinge integrity, clamp integrity, and grip strength. Based on the test results, design and assembly integrity remain substantially equivalent to the predicate device. |
| **Conclusions:** | The AMT Bridle™ - Nasal Tube Retention System is substantially equivalent to the predicate device cleared under K030784 in intended use, patient population, design, biocompatibility and testing criteria, and method of operation. |